

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

W. R. GRACE & CO.-CONN.,

Plaintiff,

v.

ELYSIUM HEALTH, INC.,

Defendant.

C.A. No. 20-1098-CFC

FILED UNDER SEAL

**PLAINTIFF’S OPENING BRIEF IN SUPPORT OF ITS MOTION TO
DISMISS DEFENDANT’S INEQUITABLE CONDUCT COUNTERCLAIMS
AND STRIKE RELATED AFFIRMATIVE DEFENSE**

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I. Introduction

At the *Markman* hearing in this action, the Court denied Elysium’s motion to amend its answer and counterclaims to add inequitable conduct counterclaims and affirmative defenses on futility grounds. The Court noted that Elysium’s pleading was deficient for several reasons. For example, Elysium failed to allege “but-for materiality” because it did not plead facts showing that Grace sold *the claimed inventions*, crystalline Forms I and II of nicotinamide riboside chloride (“NRCI”), prior to the critical dates of the patents-in-suit. It also failed to tie any of its allegations to the claims of the patents-in-suit and their limitations. In addition, Elysium failed to allege deceptive intent because it did not plead facts showing that individuals at Grace knew of the alleged sales in question, knew they were material, and failed to disclose them with the specific intent to deceive the USPTO. The Court granted Elysium leave to attempt to correct the deficiencies in a new amended pleading. As discussed below, Elysium’s new amended pleading does not cure any of these defects. Thus, the Court should dismiss Elysium’s inequitable conduct counterclaims and strike its related affirmative defense.

II. Background

This litigation concerns NRCI and nutraceutical products containing it. NRCI can exist in several solid-state forms, including amorphous forms and multiple crystalline forms. To determine the solid-state form of an NRCI sample—

and to distinguish one form from another—scientists must use one or more analytical methods, for example, powder x-ray diffraction (“PXRD”), infrared spectroscopy (“IR”), and/or differential scanning calorimetry (“DSC”). (*See* D.I. 84 at 3.) It is ***not*** possible to identify a crystalline form based upon visual inspection of a sample alone. (*See id.* at 25.)

The patents-in-suit are U.S. Patent Nos. 10,323,058 (“the ’058 patent”); 10,233,207 (“the ’207 patent”); and 10,189,872 (“the ’872 patent”). The ’058 and ’207 patents claim “crystalline Form I of nicotinamide riboside chloride,” while the ’872 patent claims “crystalline Form II of nicotinamide riboside chloride.” Consistent with the intrinsic evidence and the scientific principles discussed above, the Court construed these terms to mean “[c]rystalline Form I [or Form II] of nicotinamide riboside chloride..., ***which can be identified by one or more of the analytical methods described in the [patent’s] specification.***” (D.I. 109, emphasis added.) Each patent also claims, for example, crystalline Form I or crystalline Form II NRCl “that is characterized by a powder X-ray diffraction [PXRD] pattern substantially as shown in” a figure. The Court construed these terms to mean that the crystalline Form I or Form II NRCl is “identifiable by reference to” a PXRD pattern “largely but not wholly” as shown in the figure. (*Id.*, emphasis added.)

Thus, under the Court’s claim constructions, whether a sample contains the crystalline forms claimed in the patents-in-suit is determined by performing one or

more of the specified analytical methods (e.g., PXRD) and analyzing the results. Indeed, during claim construction both Grace and Elysium agreed that testing was required to identify the crystalline forms as claimed; the parties merely disagreed over the quantity of testing required. (*See* D.I. 84 at 5, 11-12.) Neither party argued that a form could be identified by visual inspection without testing, and neither the Court's claim constructions nor the patent specifications permit this. In fact, the '058 patent teaches that Form I NRCI an exist in several different morphologies having "color variations," as well as different physical appearances and bulk densities. (*See, e.g.,* '058 patent Fig. 3, 2:59-61, 8:57-9:15.)

III. Legal Standards

The Court denied Elysium's motion to amend on futility grounds, but granted Elysium leave to attempt to correct the deficiencies of its prior amended pleading by filing a new one. (*See* Oral Order, April 14, 2022.) "[T]he standard for assessing futility of amendment is the same standard of legal sufficiency that applies [to a motion to dismiss] under Fed. R. Civ. P. 12(b)(6)." *Invista N. Am. S.a.r.l. v. M&G USA Corp.*, No. CV 11-1007-SLR-CJB, 2013 WL 12304544, at *3 (D. Del. May 3, 2013). As such, the Court should evaluate Elysium's new pleading using the same standards it applied to the prior one.

"To survive a motion to dismiss, a [pleading] must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'"

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “A pleading that offers ‘labels and conclusions’ or a ‘formulaic recitation of the elements of a cause of action will not do.’ Nor does a complaint suffice if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’” *Id.* (quoting *Twombly*, 550 U.S. at 555, 557). Moreover, the Court is not “obligated to accept as true bald assertions, unsupported conclusions and unwarranted inferences, or allegations that are self-evidently false.” *Rader v. ShareBuilder Corp.*, 772 F. Supp. 2d 599, 603 (D. Del. 2011), *aff’d* 497 F. App’x 171 (3d Cir. 2012)(internal quotation marks omitted). The court may consider the allegations in the pleading, attached exhibits, and matters of public record. *Invista*, 2013 WL 12304544, at *3.

Elysium seeks to add claims and defenses asserting inequitable conduct, which occurs when ““(1) an **individual** associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a **material** fact, failed to disclose material information, or submitted false material information; and (2) the **individual** did so with a **specific intent to deceive**”” the United States Patent and Trademark Office (“PTO”). *Boston Scientific Corp. v. Nevro Corp.*, 2020 U.S. Dist. LEXIS 168563, *7 (D. Del. Sept. 15, 2020) (Connolly, J.) (quoting *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009)) (emphasis added)). “In other words, the accused infringer must prove by clear and

convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011).

Inequitable conduct allegations are subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b), which states that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Thus, “the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen*, 575 F.3d at 1328. And “although ‘knowledge’ and ‘intent’ may be averred generally,” the pleading “must include sufficient allegations of underlying facts from which a court may reasonably infer that a ***specific individual*** (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a ***specific intent*** to deceive the PTO.” *Id.* at 1328-29 (emphasis added). “A pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation” is insufficient. *Id.* at 1326-27. Elysium’s inequitable conduct counterclaims and affirmative defenses “rise or fall together” because both must satisfy Rule 9(b). *St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, No. 12-441-RGA, 2014 WL 2622240, at *1, n.1 (D. Del. June 11, 2014).

IV. Argument

A. Elysium Fails to Plead But-For Materiality

1. Elysium Pleads No Facts Showing that the Claimed Crystalline Forms Were Sold

Like its previous attempt, Elysium’s new amended pleading fails to allege materiality. It is well-settled that “materiality” means “but-for materiality,” *i.e.*, that the “PTO would not have allowed a claim had it been aware of the undisclosed prior art.” *Therasense*, 649 F.3d at 1291 (emphasis added). Here, Elysium contends that Grace employees failed to disclose sales of or offers to sell NRCI before the critical dates of the Patents-in-Suit,¹ which Elysium contends would have constituted an “on-sale bar” under 35 U.S.C. § 102. (Ans. ¶¶77-94.) Elysium was required to support this allegation with facts from which the Court could “reasonably draw the inference that the patents **would not have issued but for the alleged omission.**” *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 383 (D. Del. 2012)(emphasis added); *see also Pfizer Inc. v. Teva Pharms. USA, Inc.*, 803 F. Supp. 2d 409, 432 (E.D. Va.), *amended*, 803 F. Supp. 2d 464 (E.D. Va. 2011)(“a party must make an *initial showing* from which it may be *plausibly* inferred that...the information not disclosed was but-for material to the prosecution

¹ Elysium apparently does not dispute that the priority date for each Patent-in-Suit is the filing date of the earliest U.S. Provisional Patent Application the patent claims priority to, *i.e.*, July 24, 2014 for the ’058 and ’207 patents and March 9, 2015 for the ’872 patent. Thus, the relevant “critical dates” for § 102(b) are July 24, 2013 and March 9, 2014, respectively.

of the patent”). Thus, at a minimum, Elysium needed to plead facts permitting a reasonable inference that the NRCI allegedly sold contained crystalline Form I and/or Form II NRCI satisfying all limitations of at least one claim of each patent-in-suit. *See Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1352 (Fed. Cir. 2002)(holding that on-sale bar requires a showing that the product sold “embodied all of the limitations of [a] claim or would have rendered that claim obvious”); *see also Therasense*, 649 F.3d at 1291. Indeed, this Court noted that one of the “biggest weaknesses” of Elysium’s prior pleading was its failure to plead any facts concerning the crystalline form of the NRCI Grace allegedly sold prior to the critical dates. (*See* D.I. 120 at 82:14-18.)

Elysium’s new pleading does nothing to cure this glaring defect. Elysium alleges, in conclusory fashion, that Grace sold crystalline NRCI containing both Form I and Form II NRCI prior to the critical dates. (Ans. ¶¶ 45, 52.) But the only “facts” Elysium pleads in support of these allegations are [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Even

if these statements were true (they are not, as discussed below), they still would not amount to a plausible allegation of but-for materiality.

The claims of the Patents-in-Suit are directed to two *specific* crystalline forms of NRCl, not to “crystalline” NRCl generally. And, as discussed above, Forms I and II are neither defined nor identified by visual appearance. (*See* Section I *supra*.) To the contrary, under the Court’s claim constructions, Forms I and II are “identified by one or more of the analytical methods described in the [patent’s] specification.” (D.I. 109 at 1, emphasis added.) And various dependent claims require that Form I and Form II be “identifiable by reference to” specific data points. (*Id.*) Elysium’s pleading must assert facts permitting a reasonable inference that the batches in question contained Form I or Form II as identified by one or more analytical methods. It does not. Grace produced all of its analytical data for each of its NRCl batches dating back to 2013. The fact that Elysium does not cite a single shred of analytical data to support its allegations is telling and fatal to its claims.

A district court rejected similar allegations in a case involving *Walker Process* fraud, an antitrust claim that employs the same but-for materiality standard as inequitable conduct claims under *Therasense*. *See United Food & Com. Workers Unions & Emps. Midwest Health Benefits Fund v. Novartis Pharms. Corp.*, No. 15-CV-12732, 2017 WL 2837002, at *15 (D. Mass. June 30, 2017), *aff’d*, 902 F.3d 1 (1st Cir. 2018). There, the patent at issue claimed the β -crystalline form of imatinib mesylate. *Id.* at *2. The plaintiffs alleged that two

withheld prior art references that disclosed imatinib mesylate but did not mention the β -crystalline form were but-for material. *Id.* at *15. The court, citing *Exergen*, rejected these allegations because the Plaintiffs failed to show how either reference was material to any claim of the patent at issue. *Id.* The Court stated that it “cannot infer that [the references] plausibly are material where they neither discuss the β -crystalline form of the mesylate salt specifically nor mention methods for creating it.” *Id.*

In addition, several of Elysium’s insufficient “factual” allegations concerning the appearance and manufacture of the batches in question are unwarranted inferences or self-evidently false assertions that the Court need not—and should not—accept as true. *See Rader*, 772 F. Supp. 2d at 603. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

2. Elysium Fails to Tie Its Allegations to Specific Claims and Limitations

At the *Markman* hearing, the Court observed that Elysium’s prior amended pleading did not satisfy *Exergen*’s requirement that inequitable conduct allegations be tied to specific claims and limitations. (*See* D.I. 120 at 71:7-9, 11-12; 73:18, 82:19-24.) Given that the Court has now construed the claims, Elysium should have attempted to cure this defect in its new pleading. (*See id.* at 73:13-25.) But Elysium’s new amended pleading makes no effort whatsoever to tie its allegations to specific claims and limitations.

Exergen requires pleadings “to identify which claims, and which limitations in those claims, the [allegedly] withheld references are relevant to, and where in those references the material information is found—i.e., the ‘what’ and ‘where’ of the material omissions.” *Exergen*, 575 F.3d at 1329. “Such allegations are [also] necessary to explain both ‘why’ the withheld information is material and not cumulative, and ‘how’ an examiner would have used this information in assessing the patentability of the claims.” *Id.* at 1329-30. Elysium’s pleading does not even

recite *a single claim* that would not have issued but for the alleged sales in question, let alone identify where the limitations of specific claims can be found in the allegedly withheld information. Elysium’s vague, general references to “the claims” and “Asserted Patents” are plainly insufficient. (*See, e.g.,* Ans. ¶¶ 73, 76.)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This failure to “cite the specific claims...that would be deemed unpatentable in light of undisclosed information” falls far short of *Exergen’s* requirements and constitutes sufficient grounds to dismiss Elysium’s claims and strike its defense. *Milwaukee Elec. Tool Corp. v. Hitachi Koki Co.*, No. 09-C-948, 2012 WL 1952977, at *8 (E.D. Wis. May 29, 2012); *see also Emerson Elec. Co. v. Suzhou Cleva Elec. Appliance Co.*, No. 4:13-CV-01043 SPM, 2014 WL 3600380, at *4 (E.D. Mo. July 22, 2014) (holding that “generalized statements” that “fail[ed] to identify which claims and limitations...relate to Emerson’s alleged earlier product sales” were insufficient).

3. Elysium's Pleading Applies the Wrong Legal Standard For Materiality

Elysium's inequitable conduct allegations are based upon a fundamental misunderstanding of the legal standard for "materiality." For example, Elysium alleges that purported "pre-application critical date offers to sell and sales of crystalline nicotinamide riboside chloride would have been highly material to the US PTO patent examiner" and that the purported sales "create a *prima facie* case of unpatentability of the claims of the Asserted Patents, which...would have led the patent examiner to issue a rejection thereby requiring further investigation into the crystalline nicotinamide riboside chloride." (Ans. ¶ 73.) But relevance to the Examiner, making out a *prima facie* case, or requiring further investigation are not enough. Elysium needed to plead facts from which the Court could "reasonably draw the inference that the patents **would not have issued but for the alleged omission,**" i.e., "but-for materiality." *XpertUniverse*, 868 F. Supp. 2d at 383 (emphasis added). Indeed, the Federal Circuit rejected and overturned an older materiality standard based on whether a "reasonable examiner" would have considered the allegedly withheld information "important" or "relevant." See *Therasense*, 649 F.3d at 1288-90 (overruling *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed.Cir.1984)).

Nevertheless, the alleged offers or sales in question would not have even created a *prima facie* case leading to a rejection. A preponderance of the evidence

standard applies to Examiner rejections. That is, an Examiner may only reject a claim if, in view of the prior art and evidence of record, it is more likely than not that the claim is unpatentable. MPEP 706 (9th ed. Rev. 10.2019, June. 2020).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Without any evidence that the batches in question contained crystalline Form I and/or Form II as claimed in the patents-in-suit, the Examiner could not reject the claims based upon the prior sales.

In fact, the Patent Trial and Appeal Board rejected arguments like Elysium's in *Ex Parte Zimmerman*, No. 2003-0919, 2003 WL 25277881 (B.P.A.I. Nov. 24, 2003). There, the examiner rejected claims to the β -crystal form of imatinib mesylate as anticipated by a prior art reference that disclosed imatinib mesylate but was "silent as to the existence of one or more [crystalline] forms." *Id.* at *3. The examiner sought to "shift the burden of persuasion to applicants" to establish that the β -crystal form was "not inherently produced" by the procedures disclosed in the prior art reference. *Id.* On appeal, the Board held that this was reversible error. *Id.* The Board noted that the examiner failed to point to any evidence "establishing a reasonable basis for concluding" that the imatinib mesylate of the prior art "meets all limitations of the appealed claims." *Id.* Thus, examiner could not put

the applicant to the “burdensome task” of proving that the prior art did not contain the claimed crystal form without providing any evidence or scientific reasoning in support of the examiner’s position. *Id.* at *4.

Here, Elysium pleads no facts showing that the batches in question contained Form I or Form II meeting all limitations of any claim. Thus, as in *Zimmerman*, these batches would not even have provided the Examiner a basis to reject the claims during prosecution. And, in any event, the batch records certainly do not establish “but-for” materiality.

* * *

Elysium’s failure to plead but-for materiality with particularity is fatal to its inequitable conduct claims. Thus, the Court should dismiss Elysium’s inequitable conduct counterclaims and strike its affirmative defense.

B. Elysium Does Not Plead that a Specific Individual Had the Requisite Knowledge and Deceptive Intent

In addition to materiality, Elysium must assert “sufficient allegations of underlying facts from which a court may reasonably infer that a *specific individual* (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” *Exergen*, 575 F.3d at 1328-29. Put another way, Elysium must plead that a specific individual knew of the alleged offers or sales, knew that they were material, and made a deliberate decision to withhold

them. *Therasense*, 649 F.3d at 1290. As discussed in detail above, Elysium has not pled facts showing that Grace offered or sold Form I NRCl, Form II NRCl, [REDACTED] [REDACTED] prior to the critical dates. (*See* Section A.1. *supra*.) But even assuming it had, Elysium fails to plead that any specific individual had the required knowledge and acted with deceptive intent.

Elysium posits that a laundry list of identified and unidentified Grace employees committed inequitable conduct in this case:

- a) Erik C. Carlson, one of the named inventors of the Asserted Patents,
- b) the three other inventors of the Asserted Patents, and
- c) other individuals at Grace (including at a minimum Brett Reynolds, Grace’s Global Business Director, and those involved in the communications discussed beginning at paragraph 67, below)

(Ans. ¶ 45.) Elysium also repeatedly references Grace’s knowledge or actions allegedly taken by Grace. (*See, e.g., Id.* ¶¶ 72-76.) But “[t]he duty of candor and good faith in dealing with the PTO applies to individuals, not organizations.” *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 307 (D. Del. 2013). And “vague allegations [that] could implicate all or none of the individuals who had dealings with the PTO” “do[] not allow the court to reasonably infer that a specific individual both knew of the [allegedly] invalidating information and had a specific intent to deceive the PTO.” *Id.* Here, Elysium’s listing of “other inventors” and unnamed “other individuals at Grace” does not permit the Court to infer that a

specific individual concealed material information with a specific intent to deceive the USPTO.

In *XpertUniverse, Inc. v. Cisco Sys., Inc.*, for example, the court concluded that the use of “qualifiers that either Zelkin, or ‘one or more’ of the other inventors, knew about the prior sales and art and their materiality” was insufficient because it “diluted” the allegations and “afford[ed] the possibility that Zelkin, the only specific individual named, did not know about them at all.” 868 F. Supp. 2d at 381. The Court further held that “[d]ropping Zelkin’s name in the scrum of ‘XU personnel including at least Abraham Zelkin or one or more of the other individuals listed as an inventor’ fails to meet the pleading standard for ‘who’ deceived the PTO.” *Id.* Indeed, the Federal Circuit and this Court have repeatedly rejected generalized allegations like Elysium’s. *See, e.g., Exergen*, 575 F.3d at 1329 (holding that allegations directed to “Exergen, its agents and/or attorneys” were deficient because they failed to identify the specific individual(s) who allegedly deceived the PTO); *Senju*, 921 F. Supp. 2d at 307 (holding that allegation that “Senju [Pharma], Kyorin, the inventors and/or those acting on their behalf made the alleged misrepresentations and omissions before the PTO” were insufficient).

Elysium’s pleading fails to allege that any specific individual knew of the purported offers or sales, knew they were material, and withheld them with

deceptive intent. For example, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In short, Elysium fails to plead facts showing that Mr. Carlson knew of the alleged offers or sales or that he knew of their materiality.

As to Brett Reynolds, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Elysium also pleads no facts supporting an inference that

[REDACTED]

[REDACTED]

[REDACTED] As such, Elysium fails to plead that Mr. Reynolds knew of the alleged materiality of the alleged offers or sales.

Because Elysium fails to plead with particularity who knew of the purported pre-critical date offers or sales, *and* knew of their alleged materiality, *and also* failed to disclose them to the PTO with deceptive intent, its inequitable conduct claims should be dismissed and its affirmative defense stricken.

C. Elysium Does Not Establish that Grace Wrongfully Destroyed Evidence

Elysium appears to suggest that its failure to adequately plead the elements of inequitable conduct is a consequence of Grace’s purported spoliation of evidence concerning the crystalline form of the NRCl allegedly sold. (*See* Ans. ¶¶ 72-76.) As an initial matter, it is unclear how Elysium can have a “Rule 11 basis” to allege that [REDACTED]

[REDACTED] if Grace supposedly destroyed the evidence required to make that determination. (*See* D.I. 120 at 81:6-9.) In any case, Elysium fails to plead any facts whatsoever supporting these baseless accusations.

Elysium offers only bare and conclusory allegations concerning spoliation, such as that “on information and belief, neither Grace nor anyone associated with

Grace’s patent prosecution preserved information sufficient to test the crystal form of nicotinamide riboside chloride offered for sale and sold.” (Ans. ¶ 72.) But Elysium does not “set[] forth the specific facts upon which [Elysium’s] belief is reasonably based” and “provides neither the ‘information’ on which it relies nor any plausible reasons for its ‘belief.’” *Exergen*, 575 F.3d at 1330-31. Elysium further alleges that unspecified Grace actions led to “the apparent alteration or destruction or degradation of such evidence, *i.e.*, its spoliation.” (*Id.* ¶ 74.) These allegations are “speculative” at best. *See Twombly*, 550 U.S. at 555. Elysium does not plead, for example, (a) what evidence existed; (b) who destroyed, altered, or “degraded,” it; (c) when these events occurred; or (d) why or under what circumstances the evidence was destroyed, altered, or “degraded.” Moreover, it is not even clear what “degradation” of evidence means, how Grace was responsible for such degradation, or how “degradation” could amount to spoliation.

In fact, Grace produced batch records and analytical data for its NRCI batches dating back to at least 2013. Elysium pleads no specific facts suggesting that any information concerning the crystalline form of Grace’s NRCI was destroyed. The pleading requirements for inequitable conduct set forth by *Exergen* and *Therasense* would be totally eviscerated if such bare allegations of spoliation without specific factual support could sustain inequitable conduct claims.

Furthermore, even if such evidence existed and was destroyed, Elysium fails to plausibly allege that Grace had an obligation to preserve it. Elysium does not plead any facts showing that Grace anticipated litigation with Elysium before the last of the Patents-in-Suit issued on June 18, 2019. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Elysium has publicly claimed that it uses a proprietary, patent-pending form of NRCl. (*See* Ex. B, GRACE0007103-117.) Elysium pleads no facts showing that Grace anticipated litigation with Elysium before it tested Elysium's product in late 2019 to 2020 (after the last of the three Patents-in-Suit issued) and learned that Basis[®] contains crystalline form I and crystalline form II NRCl as claimed by the Patents-in-Suit.

V. Conclusion

The Court should dismiss Elysium's inequitable conduct counterclaims under Federal Rule of Civil Procedure 12(b)(6) and strike its inequitable conduct affirmative defense under Rule 12(f).

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CERTIFICATE OF COMPLIANCE WITH
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I certify that the foregoing brief satisfies the type volume limitations specified by Local Rule 7.1.3(4), as modified by Judge Colm F. Connolly's "Standing Order Regarding Briefing in All Cases." I certify that the text of this brief is presented in 14-point Times New Roman font and that, based upon the word count of the word-processing system used to prepare this brief, the number of words contained in the text of this brief is 4995.

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CERTIFICATE OF SERVICE

I hereby certify that on May 26, 2022, copies of the forgoing OPENING BRIEF were served in the manner indicated below.

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